

February 8, 2007 Correspondence

*(1) Why did West Texas Hospital receive a Medicare provider number from CMS during the MMA mandated moratorium on physician-owned specialty hospitals?*

- a. Did West Texas Hospital file a request for an advisory opinion to determine if it qualified for the “under development” exception to the MMA moratorium? If so, please provide any documentation.*
- b. Please describe in detail the events surround the application for and granting of a Medicare provider number for West Texas hospital.*

**Response:** The moratorium included in the Medicare Modernization Act (MMA) did not prevent physician-owned specialty hospitals from opening and receiving a Medicare provider agreement during the 18-month moratorium. Rather, Section 507 of the MMA (“the moratorium”) prohibited physician investors in specialty hospitals from referring Medicare patients to a specialty hospital for all inpatient and outpatient services (and certain other designated health services) from December 8, 2003 through June 7, 2005, and prohibited the hospital from submitting any claims for items or services rendered pursuant to a prohibited referral. The statutory moratorium did not provide a basis for the Centers for Medicare & Medicaid Services (CMS) to deny provider agreements to physician-owned specialty hospitals. Excluded from the 18-month moratorium were those physician-owned specialty hospitals that were found to be under development as of November 18, 2003.

Section 5006(a)(1) of the Deficit Reduction Act (DRA) required HHS to develop a Strategic and Implementing Plan to address certain issues relating to physician investment in “specialty hospitals.” As part of the plan, HHS attempted to ascertain whether there were hospitals that did not seek an advisory opinion as to whether they were subject to the MMA moratorium but which, in fact, were specialty hospitals, and which may have violated the moratorium. Based upon a review of Medicare claims data, we determined that West Texas Hospital was a specialty hospital. In order to determine whether West Texas Hospital was in compliance with the moratorium, CMS sent a letter on April 20, 2006 and a follow-up letter on June 7, 2006 requesting additional information concerning the hospital’s ownership, a list of Major Diagnostic Categories (MDCs) and the Diagnosis Related Groups (DRGs) within those MDCs by type (medical or surgical) for all inpatient discharges since the beginning of the Hospital’s operation through June 7, 2005. West Texas Hospital’s Chief Executive Officer (CEO) responded that it did not bill for any services based upon prohibited referrals before the expiration of the moratorium, and this was later confirmed by our data analysis. Accordingly, it does not appear that the hospital violated the moratorium, and the hospital did not request an advisory opinion to determine if it qualified for the “under development” exception to the MMA moratorium.

Upon the expiration of the MMA moratorium, CMS announced its decision to review its processes for approving and making payments to new hospitals. On June 9, 2005, CMS instructed its regional offices not to issue new specialty hospital provider agreements or authorize an initial survey by the state survey agency for new specialty hospitals that had not requested an advisory opinion or whose application for enrollment was not pending. Medicare fiscal intermediaries were also instructed to temporarily suspend the processing of specialty

hospital enrollment applications until January 2006. Section 5006 of the DRA extended the suspension on enrollment until August 8, 2006.

The Medicare fiscal intermediary for Texas (Trailblazers) received an enrollment application from West Texas Hospital on June 27, 2006. Trailblazers did not follow the CMS instructions to temporarily suspend the processing of applications from specialty hospitals. CMS instructed all fiscal intermediaries to obtain a written statement containing a projection, based upon DRG/MDC and type (medical/surgical), for all patient cardiac, orthopedic, or surgical discharges the applicant hospital expected in its first year of operation. If the applicant's projections indicated that 45 percent or more of inpatient cases would fall in either cardiac, orthopedic, or surgical care, the applicant would have been considered a specialty hospital subject to the suspension. Trailblazers did not request this type of information and on July 6, 2006, it recommended to the CMS Regional Office that a provider agreement be issued to West Texas Hospital. CMS issued a provider agreement to West Texas Hospital with an effective date of May 19, 2005, the date the hospital received JCAHO accreditation.

After discovering that our instructions to temporarily suspend the processing of applications from specialty hospitals were not followed with regard to West Texas Hospital's application, we directed Trailblazers to pull all enrollment applications that were received during the enrollment suspension period (i.e., June 9, 2005 through August 9, 2006). This was done to determine the extent of the fiscal intermediary's compliance with our instruction. We have determined that of 20 applications received during the enrollment suspension, Trailblazers did not adhere to our instructions in three separate instances. In two of the instances, no inquiry was made to determine whether the hospital applicant was a specialty hospital. However, neither of those hospital applicants received a provider agreement from CMS. In the third instance, the applicant's projection was slightly over our threshold (47 percent) and the application should have been suspended.

We are currently contacting each fiscal intermediary to have it check its adherence to our instructions concerning the temporary suspension on processing of enrollment applications from specialty hospitals. As soon as this information is received, we will forward our findings to you.

*(2) Provide a list of all Medicare and Medicaid reimbursements paid to West Texas Hospital or any provider affiliated with West Texas Hospital from 2005 to the present.*

- a. Were any of the Medicare payments made during the statutorily mandated moratorium on payments?*
- b. If so, has CMS initiated any action to collect the payments made during this period? If not, why not?*

Response: West Texas Hospital did not bill Medicare for any services until after the expiration of the moratorium. Please see Attachments 1a and 1b for a list of Medicare reimbursements to date. Attachment 2 contains a preliminary list of Medicaid reimbursements, as supplied by the Texas Medicaid fiscal agent. We have requested that this spreadsheet be revised to capture not

only diagnosis code but also procedure code. The revised data run should be completed by February 27.

*(3) Provide a list of all physician owners of West Texas Hospital.*

Response: Because West Texas Hospital did not bill the Medicare program for any services based upon prohibited referrals before the expiration of the moratorium, we have not compiled a list of all the hospital's physician owners. Further, because West Texas Hospital did not answer our survey, we do not have the information readily available. If you are still interested in receiving this information even though the hospital did not violate the MMA moratorium, we will send it under separate cover.

*(4) Has CMS conducted any surveys of West Texas Hospital? If so, provide a copy of all such surveys.*

Response: An investigation of the specific facts of this case was scheduled shortly after the adverse event—the onsite portion of the investigation began on February 7, 2007 and the final exit conference with the facility was held on February 14, 2007. On February 22, 2007, the hospital was notified that the investigation revealed that the hospital was not in compliance with Medicare Conditions of Participation (CoPs) and that the hospital's accreditation would no longer be deemed as adequate to establish that the CoPs were met. Due to the evidence of serious and immediate threat to patient health and safety, CMS also notified the hospital that its Medicare agreement will terminate on March 17, 2007 unless the problems are corrected prior to that time. A copy of the termination notice to the facility is included in Attachment 3. The complaint investigation findings will be made publicly available according to standard protocols once the hospital has had an opportunity to review and respond to them. The following CoPs were cited in the CMS communication to the hospital:

- **42 CFR 482.12 Governing Body** (governing body's legal responsibility for conduct of the hospital);
- **42 CFR 482.13 Patient Rights** (protecting and promoting the rights of each patient, including the right to receive care in a safe setting);
- **42 CFR 482.23 Nursing Services** (responsibility to have an organized nursing service that provides 24-hour nursing services, furnished or supervised by a registered nurse, including adequate numbers of nursing staff); and
- **42 CFR 482.55 Emergency Services** (responsibility to meet the emergency needs of patients in accordance with acceptable standards of practice).

Prior to the most recent complaint investigation, CMS conducted one earlier complaint investigation survey of West Texas Hospital, on January 31, 2006. The complaint was not

patient specific, and the investigation did not substantiate the complaint. The survey report is included in Attachment 4.

As you may know, West Texas Hospital was accredited by the Joint Commission on May 19, 2005, and thus it was deemed as having met the Medicare CoPs at the time it was certified as a Medicare-participating provider. CMS does not routinely survey hospitals that enter the Medicare program via accreditation by either the Joint Commission or the American Osteopathic Association. However, such hospitals may be surveyed by CMS in response to a credible complaint alleging noncompliance with a Medicare CoP, as was the case with the January 31, 2006 investigation. If the complaint validates violation of a CoP, the hospital's deemed status is removed and it is placed under the jurisdiction of the State Survey Agency that contracts with CMS to conduct surveys. A more comprehensive survey of the entire facility would then be conducted. Since the earlier 2006 West Texas Hospital complaint investigation was not substantiated, the hospital retained its deemed status and remained under the jurisdiction of the Joint Commission. However, in the case of the most recent investigation, the survey found evidence of serious and immediate threat to patient health and safety. Accordingly, CMS removed the hospital's deemed status and the hospital is now under State survey agency jurisdiction.

*(5) Did West Texas Hospital provide responses to CMS's survey on physician-owned specialty hospitals that was sent in an effort to collect information for the Strategic and Implementing Plan for Specialty Hospitals? If so, please provide a copy of West Texas Hospital's responses.*

Response: CMS's survey on physician-owned specialty hospitals was a voluntary collection effort and the CEO for West Texas Hospital declined to participate in the survey. As we stated in the Final Report to Congress containing the Strategic and Implementing Plan for Specialty Hospitals, we are implementing a regular mandatory disclosure process, and will begin with those hospitals, such as West Texas Hospital, that did not respond to our survey questions on investment interests and compensation arrangements.

*(6) Does West Texas Hospital provide notification to patients prior to surgery that, in the event of an emergency, they may be transferred to another hospital and that the facility may not have a physician on site during the post-operative recovery period?*

Response: At present there is no Medicare requirement for such a disclosure. In reviewing the admission packet information, hospital policies and other medical record documentation, we found no evidence that West Texas Hospital provides notification to patients prior to surgery that in the event of an emergency they may be transferred to another hospital and that the facility may not have a physician on-site during the post-operative recovery period. In addition to our current requirements, we plan to issue a proposed rule later in 2007 that is designed to address patient safety measures.

*(7) How many times in the past has West Texas Hospital called 911 to transfer a patient to another hospital in an emergency situation?*

Comprehensive 911 information is not typically collected or tracked, nor generally available to CMS. However, the Abilene area has an arrangement whereby all 911 calls are handled through one single organization. We were therefore successful in working with the Texas Department of State Health Services and Abilene officials to get the information that you have requested. Since May 2005—when West Texas Hospital opened—and February 8, 2007, there have been 15 instances or “runs” that have occurred where West Texas Hospital called 911 to transfer a patient to another hospital in an emergency situation.

Please be assured that it is never acceptable for a Medicare-participating hospital to rely upon 911 as its response to the development of an emergency medical condition in one of its patients, in lieu of having its own capability to provide emergency treatment. Although the provision of emergency services as an organized department or distinct service line of the hospital is optional under the Medicare hospital CoPs, the CoPs also state explicitly that all hospital patients have a right to receive care in a safe setting and that hospitals without emergency departments must still have written policies for the appraisal of emergencies, initial treatment, and referral.

In addition, the Medicare CoPs state explicitly that the hospital’s medical staff is responsible for the quality of medical care provided to the hospital’s patients. Every hospital’s governing body is required to assure that a physician is responsible for the care of each Medicare patient with respect to any medical problem present on admission or that develops during hospitalization. Moreover, where a hospital has an organized emergency department/service, it is expected to have adequate medical and nursing personnel qualified in emergency care to meet the hospital’s anticipated emergency needs. Therefore, calling 911 to handle a hospital patient’s emergency medical condition would not be considered consistent with these regulatory requirements to the extent that the 911 action serves as a substitute for any of the hospital’s required capabilities. In this case, Texas State law requires hospitals to have an emergency department and West Texas Hospital described itself to the public, State, and CMS, as having such capability.

As indicated in the strategic and implementing plan mandated in the DRA, we believe it is appropriate to issue further guidance on what we expect of hospitals in terms of emergency service capability. For example, we are considering further guidance to clarify that even in hospitals without emergency departments, whenever it is necessary for a hospital to refer a patient to another hospital, the referring hospital must have appropriate procedures and qualified staff for appraisal of the patient and the provision of initial treatment until the patient can be transferred. The referring hospital should provide the receiving hospital with information that it possesses and that is necessary for continued treatment of the patient. Such clarification may be important for all hospitals, but may be particularly pertinent to physician-owned specialty hospitals given that such a large percentage do not have emergency departments.